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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/711,101

08/23/2004

George Blanck

1372.183.PRC

5100

21901

7590

12/13/2006

SMITH HOPEN, PA  
180 PINE AVENUE NORTH  
OLDSMAR, FL 34677

EXAMINER

VIVLEMORE, TRACY ANN

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/711,101

Applicant(s)

BLANCK ET AL.

Examiner

Tracy Vivlemore

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 June 2006 and 27 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-13 is/are pending in the application.
- 4a) Of the above claim(s) 4-8 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 and 11-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection or objection not reiterated in this Action is withdrawn.

### ***Election/Restrictions***

Applicant's election of invention II, claims 9 and 11-13, in the reply filed on September 27, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 10 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 27, 2006.

Claims 4-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 28, 2005.

### ***Specification***

The use of the trademark "Metamorph" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Objections***

Claims 12 and 13 are objected to because of the following informalities: each of these claims is ungrammatical, reciting "wherein the an Oct-1 inhibitor". Appropriate correction is required.

### ***Response to arguments: written description***

Claims 9 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This rejection is maintained for the reasons set forth in the rejection of original claims 1-3 in the office action mailed February 2, 2006 and as clarified below.

Applicant traverses the written description rejection by stating that the application sets forth precise detail about the structural and chemical properties of the Oct-1 mechanism and that inhibitors of Oct-1 are similarly detailed by their functional characteristics coupled with the known correlation between Oct-1 function and structure. Applicant further argues that the specification discusses screening assays that can be used for identifying such inhibitors and states that the office has advanced no specific reasoning why the assays outlined in the specification would be unsuccessful in identifying other similar agents. While one might be able to identify inhibitors of Oct-1, the structure and function of Oct-1 will not lead the skilled artisan to envision

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compounds having the function recited by the amended claims, of treating a tumor *in vivo*. The claimed invention encompasses the use of inhibitors of Oct-1 of any type, including nucleic acids, antibodies and small molecules but the specification describes only a single antisense vector capable of inhibiting Oct-1 *in vitro*. Neither the specification nor the prior art describe any inhibitors of Oct-1 that treat tumors in a subject.

Applicant further states that the references cited in the action show that Oct-1 inhibiting substances are well-known in the art and that the working example provided in the specification coupled with the knowledge of the prior art is sufficient to enable the claimed genus of compounds. The examiner agrees that some inhibitors of Oct-1 are known from the prior art but these known inhibitors are not described by the prior art as able to treat tumors in a subject.

***Response to arguments: enablement***

Claims 9 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. This rejection is maintained for the reasons set forth in the scope of enablement rejection of original claims 1-3 in the office action mailed February 2, 2006. It is noted that the claims have been amended to exclude the enabled scope and embrace only non-enabled embodiments of the invention.

In traverse of the scope of enablement rejection, applicant argues that methods of modulating gene expression were known in the prior art, as evidenced by the two US patents cited, and further argues that the office has cited *per se* rules by relying on

generalized articles. Applicant is correct that methods of modulating gene expression were known in the art; however, the cited patents appear to be directed to the use of chemical modulators and do not provide evidence that delivery of nucleic acid therapeutics *in vivo* is predictable. Also, the claims are not directed to modulation of gene expression, but to treatment of tumors. The previous office action did not cite a *per se* rule, but described the state of the art regarding nucleic acid therapeutics: that delivery of nucleic acids to organisms for therapeutic purposes is unpredictable; the reference of Opalinska was cited to provide evidence of this unpredictability. Applicant further argues that the specification and the references highlighted by the office show that modulation of Oct-1 was known in the art. This argument is not persuasive because the instant claims are not directed solely to modulation, but treatment of tumors and the claims as amended are directed to methods performed in a subject and thus have only *in vivo* embodiments. Methods of *in vitro* modulation of Oct-1 known from the art do not provide evidence that nucleic acids can be predictably delivered *in vivo*. Additionally, modulation of Oct-1 for treatment of tumors was not known prior to instant specification, therefore, modulation of Oct-1 for cancer therapy was not known in the art.

Applicant further argues that the specification shows that the 5637 cell line correlates to the breadth of the claims and argues that the office has not offered any evidence that the prophetic example does not correlate. This argument appears to be that the cell line used in the working example of the specification is a model for cancer. The basis of the rejection, however, is not whether the cell line used in the example is

an acceptable model for cancer, but that the delivery of nucleic acid inhibitors is recognized in the art as unpredictable.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

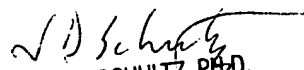
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz, can be reached on 571-272-0763. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore  
Examiner  
Art Unit 1635

TV  
November 28, 2006

  
JAMES SCHULTZ, PH.D.  
PRIMARY EXAMINER